Excess Emissions and Continuous Monitoring System (CMS)
Performance Report and/or Summary Report
Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities

SECTION I
GENERAL INFORMATION

A. Print or type the following information for each facility for which you are submitting an excess emissions and CMS performance report and/or summary report (§63.9(b)(2)(i)-(ii))

Responsible Official's Name/Title		
Matthew Russo, Site Director		
Street Address		
60 Middletown Ave		
City	State	ZIP Code
North Haven	CT	06473
Facility Name (if different from Responsible Official's Name)		
Covidien LP		
Facility Street Address (If different than Responsible Official's Street Address)		
Facility Local Contact Name	Title	Phone (OPTIONAL)
Holly Donahue	EHS Manager	
City	State	ZIP Code
North Haven	CT	06473

B. Indicate the relevant standard(s) or other requirement(s) that is/are the basis for this report. (§63.5(d)(1)(ii)(D))

Basis for this report *(relevant standards or other requirements)*
Subpart O– Ethylene Oxide Emissions Standards for Sterilization Facilities

C. Are you requesting a waiver of recordkeeping and/or reporting requirements under the applicable relevant standard(s) in conjunction with this excess emissions and CMS performance report and/or summary report? (§63.10(f)(3))

☐ Yes ☒ No

If you answered yes, you must submit the application for a waiver of recordkeeping and/or reporting requirements together with this excess emissions and CMS performance report and/or summary report. The application for waiver should include whatever information you consider useful to convince the Administrator that a waiver of recordkeeping and/or reporting is warranted. (§63.10(f)(3))

D. Check the box that corresponds to the report(s) you are submitting:

☐ Summary Report Only ***(Complete Sections II and IV)***

☒ Excess Emission and CMS Performance Report and Summary Report ***(Complete Sections II, III, and IV)***

SECTION II
CERTIFICATION *(Note: you may edit the text in this section as deemed appropriate)*

Based upon information and belief formed after a reasonable inquiry, I, as a responsible official of the above-mentioned facility, certify the information contained in this report is accurate and true to the best of my knowledge.

Name of Responsible Official (Print or Type)	Title	Date (mm/dd/yy)
Matthew Russo	Site Director	07/24/2018

Signature of Responsible Official

Note: Responsible official is defined under §63.2 as any of the following: the president, vice-president, secretary, or treasurer of the company that owns the plant; the owner of the plant; the plant engineer or supervisor; a government official if the plant is owned by the Federal, State, city, or county government; or a ranking military officer if the plant is located on a military installation.

SECTION III
EXCESS EMISSIONS AND CMS PERFORMANCE REPORT

A. Excess Emissions

1. Have any excess emissions or exceedances of a parameter occurred during this reporting period? ☐ Yes ☒ No ***(if no, go to B.1.)*** (§63.10(e)(3)(v))

2. If you answered yes, complete the following table ***for each period*** of excess emissions and/or parameter monitoring exceedances, as defined in the relevant standard(s), that occurred ***during*** startups, shutdowns, and/or malfunctions of your affected source, ***or during periods other than*** startups, shutdowns, and/or malfunctions of your affected source. (§63.10(c)(7)-(11))

Note: Use a separate line for each period of excess emissions and/or parameter monitoring exceedances of your affected source.

Nature of Event or Problem		Excess Emissions and/or Parameter Monitoring Exceedances Occurred:							
Excess Emissions	Parameter Monitoring Exceedance	During Startup	During Shutdown	During Malfunction	During Another Period	Start Date (mm/dd/yyyy)	Completion Date (mm/dd/yyyy)	Nature and Cause of any Malfunction (if known)	Corrective Action Taken or Preventive Measures Adopted
☐	☐	☐	☐	☐	☐				
☐	☐	☐	☐	☐	☐				
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☐	☐	☐	☐	☐	☐				

B. CMS Performance

1. Has a CMS been inoperative (except for zero/low-level and high-level checks), out of control (as defined in §63.8(c)(7)(i)), repaired, or adjusted during this reporting period? ☒ Yes ☐ No ***(if no, go to B.3.)*** (§63.10(e)(3)(v))

Note: A CMS is out of control if (a) the zero (low-level), mid-level (if applicable), or high-level calibration drift (CD) exceeds two times the applicable CD specification in the applicable performance specification or in the relevant standard; or (b) the CMS fails a performance test audit (e.g., cylinder gas audit), relative accuracy audit, relative accuracy test audit, or linearity test audit; or (c) the COMMS CD exceeds two times the limit in the applicable performance specification in the relevant standard. (§63.8(c)(7(i))

When the CMS is out of control, the owner or operator of the affected source shall take the necessary corrective action and shall repeat all necessary tests which indicate that the system is out-of-control. The owner or operator shall take corrective action and conduct retesting until the performance requirements are below the applicable limits. The beginning of the out-of-control period is the hour the owner or operator conducts a performance check (e.g., calibration drift) that indicates an exceedance of the performance requirements established under this part. The end of the out-of-control period is the hour following the completion of corrective action and successful demonstration that the system is within the allowable limits. During the period the CMS is out-of-control, recorded data shall not be used in data averages and calculations, or to meet any data availability requirement established under this part. (§63.8(c)(7(ii))

2. If you answered yes, complete the following table ***for each period*** a CMS was out of control, repaired, or adjusted: (§63.10(c)(5)-(6), (10)-(12); §63.8(c)(8))

Note: Use a separate line for each period a CMS was out of control, repaired, or adjusted.

CMS Type	Manufacturer	Process ID Number	Start Date (mm/dd/yyyy)	Completion Date (mm/dd/yyyy)	Nature and Cause of Any Malfunction (if known)	Corrective Action Taken or Preventive Measures Adopted	Nature of the Repairs or Adjustments Made to the CMS that was Inoperative or Out of Control
Gas Chromatograph	Baseline		1/1/18	1/15/18	QC calibration was outside of allowable range per 40 CFR 60, App B, Spec 9.	QA/QC multipoint calibration and quarterly audits are now performed by a third party contractor.	On-site engineer worked with support from the GC manufacturer to adjust the unit on January 16, 2018 so it is calibrating properly. Staff adjusted the carrier regulator pressure to move the retention time to 35 seconds in order to get more accurate readings of the amount of ethylene oxide going to the GC and correct the out of control condition.
Gas Chromatograph	Baseline		4/6/18	4/18/18			

3. Indicate the total process operating time during the reporting period. (§63.10(c)(13))

Total process operating time (days)
173

SECTION IV
SUMMARY REPORT- EXCESS EMISSION AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

Note: One summary report shall be submitted for the hazardous air pollutants monitored at each affected source (unless the relevant standard specifies that more than one summary report is required, e.g., one summary report for each hazardous air pollutant monitored). (§63.10(e)(3)(vi))

A. Report Date and Submittal Reporting Period

Indicate the reporting period covered by this submittal and the date of this summary report. (§63.10(e)(3)(vi)(C), (M))

Reporting period beginning date (mm/dd/yyyy)	Reporting period ending date (mm/dd/yyyy)	Summary report date (mm/dd/yyyy)
1/1/2018	6/30/2018	7/20/2018

B. Process Description and Monitoring Equipment Information

Complete the following process description and monitoring equipment information table ***for each affected source process unit***: (§63.10(e)(3)(vi)(B), (D), (E), (F), (G), (H))

Total operating time of affected source during the reporting period (days)
173

Process unit name
Ethylene Oxide Sterilizers A and B

Process unit description
Covidien LP operates two sterilization systems (each consisting of a sterilization chamber and a primary aeration room, as well as two secondary aeration rooms that are shared by both systems). The units are used to sterilize medical devices. The devices are introduced to the sterilization chamber and sterilized using a mixture of ethylene oxide, nitrogen and steam. The sterilized product is then off-gassed; first in a primary aeration room and then a secondary aeration room. All sterilizer and primary aeration room exhausts and vents are ducted to a single stack equipped with a balancer and oxidizer. There is a combined exhaust stack for the two secondary aeration room exhausts, which exhausts directly to the atmosphere due to the low levels of ethylene oxide present.

Emission and/or operating parameter limitations specified in the relevant standard(s)
Sterilization chamber vent - reduce ethylene oxide emissions by 99% / Aeration room vent – maximum outlet concentration of 1 ppmv

Monitoring Equipment Information

Type	Latest Certification or Audit Date (mm/dd/yyyy)	Manufacturer	Model	HAPs Monitored
Temperature sensor for catalyst bed outlet	2/23/2018	LESNI	Kjaerulf Pedersen 25.611	N/A - temperature
Gas Chromatograph for vents	6/29/2018	Baseline	8900 GC	Ethylene Oxide

C. Emission Data Summary

Complete the following emission data summary table ***for each affected source***:
(§63.10(e)(3)(vi)(I))

Total operating time of affected source during the reporting period (days)
173

Percent of total source operating time during which excess emissions/parameter exceedances occurred (percent)
0%

Summary of causes of excess emissions/parameter exceedances (percent of total duration by cause)

Startup/shutdown	0%
Control equipment problems	0%
Process problems	0%
Other known causes	0%
Other unknown causes	0%
TOTAL	0%

D. CMS Performance Summary

Complete the following CMS performance summary table ***for each affected source***:
(§63.10(e)(3)(vi)(J))

Total operating time of affected source during the reporting period (days)
173

Percent of total source operating time during which CMS were down (percent)
16.5% - GC downtime

Summary of causes of CMS downtime (percent of downtime by cause)

Monitoring equipment malfunctions	0%
Nonmonitoring equipment malfunctions	0%
Quality assurance/quality control calibrations	94.88%
Other known causes	0%
Other unknown causes	5.12%
TOTAL	100%

E. CMS, Process, or Control Changes

1. Have you made any changes in CMS, processes, or controls since the last reporting period? ☐ Yes ☒ No ***(if no, end of form)*** (§63.10(e)(3)(vi)(K))

2. If you answered yes, please describe the changes below:

Changes in CMS, processes, or controls since the last reporting period

END OF FORM - Please make sure that a Responsible Official signs Section II prior to submitting the form to your EPA Regional Office or your State Air Permitting Agency, as applicable.